

Application Number 10/663,570
Response to Office Action mailed August 7, 2008

REMARKS

This Amendment is responsive to the Office Action dated August 7, 2008. Applicant has amended claims 21, 29-31, and 35, canceled nonelected claims 1-4, 9, 10, 12-19, and 43-45 and added claim 46. Claims 5-8, 11, 20, 27, 28, and 34 were canceled in a previous Amendment. Claims 21-24, 26, 29-33, 35-42 and 46 are pending.

Claim Rejection Under 35 U.S.C. § 101

In the Office Action, claims 21-24, 26, and 29-33 were rejected under 35 U.S.C. § 101. In particular, the Office Action stated that the last clause of claim 21 as previously presented appears to include part of the human body. While Applicant disagrees that claim 21 as previously presented claimed part of the human body, Applicant has amended independent claim 21 to specify that the genetic material is "adapted to cause expression of at least one of a connexin or a gap-junction," as suggested by the Examiner. Similar amendments have been made to claims 29, 30, 31, and 35. Reconsideration and withdrawal of the rejection of claims 21-24, 26, and 29-33 under 35 U.S.C. § 101 is respectfully requested.

Claim Rejection Under 35 U.S.C. § 103

In the Office Action, claims 21-24, 26, 29-33, and 35-42 were rejected under 35 U.S.C. § 103(a) as obvious over Soykan et al. (U.S. Patent No. 6,151,525, hereinafter "Soykan") in view of Heil, Jr. et al. (U.S. Patent No. 4,819,662, hereinafter "Heil") and Girouard et al. (U.S. Patent Application Publication No. 2004/0158289, hereinafter Girouard). Applicant respectfully traverses the rejection of the claims. The applied references fail to disclose or suggest the inventions defined by Applicant's claims, and provide no teaching that would have suggested the desirability of modification to arrive at the claimed invention.

With reference to independent claim 21, for example, the applied references lack any teaching that would have suggested a medical lead that includes a porous electrode and a chamber body that defines a chamber containing a polymeric matrix that absorbs a genetic material and elutes the genetic material via the porous electrode to tissue at the stimulation site, where the genetic material is adapted to cause expression of at least one of a connexin or a gap-

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junction by the tissue at the stimulation site to increase the conductivity of the tissue at the stimulation site.

In support of the rejection of independent claim 21 as being obvious over Soykan in view of Heil and Girouard, the Office Action stated that Soykan discloses a lead that delivers electrical stimulation to a tissue site and elutes genetic material from a polymeric matrix.¹ The Office Action acknowledged that Soykan does not disclose or suggest a chamber that elutes material from a porous electrode, or a genetic material that is adapted to cause expression of at least one of connexin or a gap junction. The Office Action asserted that Heil discloses "a lead with a chamber that elutes substances through a porous electrode" and Girouard discloses "providing a cardiac therapy comprising delivering connexin."² The Office Action reasoned that it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Soykan in view of Heil and Girouard to "for the purpose of providing controlled release of pharmacological agents at the site of electrical therapy and providing a cardiac therapy comprising delivering connexin for the purpose of repairing damaged heart tissue."³ Applicant respectfully disagrees with the Examiner's conclusion of obviousness.

The medical lead of independent claim 21 is not obvious over Soykan in view of Heil and Girouard. References may only be modified to reject claims as *prima facie* obvious as long as there is a reasonable expectation of success.⁴ Neither the Heil nor Soykan disclosures provide reasonable support for asserting that modifying Soykan in view of Heil to include a chamber body that includes a matrix that elutes a genetic material to tissue at a stimulation site via a porous electrode would reasonably be expected to be successful. For example, the cited art fails to provide a reasonable basis for concluding that that elution of a genetic material via a porous electrode that also delivers electrical stimulation to tissue would be successful in causing expression of at least one of a connexin or a gap-junction by the tissue at the stimulation site. Heil only discusses a matrix that elutes a drug, and does not contemplate elution of a genetic material, much less elution of a genetic material that increases the conductivity of tissue at the stimulation site.

¹ Office Action at p. 3, item 7.

² Office Action at p. 4, item 7.

³ Office Action at p. 4, item 7.

⁴ MPEP 2143.02 (I).

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A drug and a genetic material are different and may have different properties. For example, Applicant has recognized that expression of at least one of connexin or a gap-junction may provide advantages over elution of a drug, such as a desired effect that lasts longer and is more localized than that of drug.⁵ Based on the lack of disclosure within Soykan and Heil regarding the possibility of eluting a genetic material via a porous electrode, Soykan in view of Heil and Girouard fails to render Applicant's independent claim 21 obvious.

The Examiner failed to establish a rational reason for modifying Soykan in view of Heil and Girouard, and, thus, failed to establish a *prima facie* case of obviousness of claim 21. For example, the Examiner failed to identify a rational reason why one having ordinary skill in the art would have looked to Heil or Girouard to modify Soykan. While the Office Action stated that one having ordinary skill in the art would have looked to Heil to modify Soykan in order to provide "controlled release of pharmacological agents at the site of electrical therapy,"⁶ this purported reason lacks a rational underpinning.⁷ This statement appears to overlook the fact that the system disclosed by Soykan already provides controlled release of a genetic material at the site of electrical therapy. For example, Soykan discloses coating or otherwise incorporating a genetic material into a carrier, which may be an electrical stimulation device.⁸ Soykan discloses that the genetic material may be delivered in a polymeric matrix.⁹ According to the Office Action, "[t]he level of cross-linking [of a matrix] is inherently proportional to the release rate."¹⁰

Heil does not provide any indication that the porous electrode is advantageous over the coating disclosed by Soykan for releasing a genetic material, or provides some expected beneficial result over the coating disclosed by Soykan. Accordingly, the cited art does not support the Examiner's proposed reason for why one having ordinary skill in the art would have had modified Soykan in view of Heil. Indeed, absent access to Applicant's disclosure, one having ordinary skill in the art would not have had a rational reason to modify Soykan in view of Heil to release the genetic material via the porous electrode disclosed by Soykan.

⁵ Applicant's originally-filed disclosure at paragraph [0011].

⁶ Office Action at p. 4, item 7.

⁷ See MPEP 2142, citing *In re Kahn*, 441 F.3d 977, 988 (Fed. Cir. 2006) ("[R]ejections on obviousness cannot be sustained with mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.")

⁸ Soykan at col. 11, ll. 5-7.

⁹ Soykan at col. 11, ll. 15-16.

¹⁰ Office Action at p. 4, item 9.

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The Office Action also failed to provide any articulated reasoning for why one having ordinary skill in the art would have looked to Girouard to modify Soykan. The Office Action stated that one having ordinary skill in the art would have looked to Girouard to modify Soykan in order to provide "a cardiac therapy comprising delivering connexin for the purpose of repairing damaged heart tissue."¹¹ This rationale, however, is circular and lacks a rational underpinning. For example, the argument presented by the Office Action fails to identify a reason that would have even prompted a person having ordinary skill in the art to even modify the type of genetic material disclosed by Soykan. Girouard does not provide any indication that connexin is advantageous over the genetic material disclosed by Soykan, or provides some expected beneficial result over the coating disclosed by Soykan.

Independent claim 35 as amended recites a method that comprises placing a polymeric matrix into a chamber formed by a chamber body of a medical lead for elution of genetic material to tissue of a patient at a stimulation site, where the genetic material is adapted to cause expression of at least one of a connexin or a gap-junction by the tissue at the stimulation site to increase the conductivity of the tissue at the stimulation site, and where the matrix elutes the genetic material to the stimulation site via a porous electrode of the medical lead. For the reasons discussed above with respect to independent claim 21, claim 35 is patentable over the applied references.

For at least these reasons, the Examiner has failed to establish a prima facie case for non-patentability of Applicant's independent claims 21 and 35 under 35 U.S.C. § 103(a). Claims 22-24, 26, and 29-33 depend from claim 21 and claims 36-42 depend from claim 35 and are patentable over Soykan in view of Heil and Girouard for at least the reasons discussed above with respect to independent claims 21 and 35. In addition, claims 22-24, 26, 29-33, and 36-42 recite additional features that are neither disclosed nor suggested by the cited art. For example, with respect to claim 24, which depends from claim 21, the cited art fails to disclose or suggest a chamber body that is separable from the lead body. The Office Action dated August 7, 2008 failed to specifically discuss the rejection of claim 24, and, therefore, failed to meet the burden of demonstrating that claim 24 is obvious in view of the cited art.

Reconsideration and withdrawal of the rejection of the claims is respectfully requested.

¹¹ Office Action at p. 4, item 7.

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New Claim

Applicant has added claim 46 to the pending application. The applied references fail to disclose or suggest the inventions defined by Applicant's new claim 46, and provide no teaching that would have suggested the desirability of modification to arrive at the claimed inventions. As one example, the references fail to disclose or suggest a medical lead that includes a chamber body defining a chamber that contains a polymeric matrix that absorbs a genetic material and elutes the genetic material to tissue at a stimulation site within a patient via a porous electrode, where the genetic material is adapted to cause expression of at least one of a connexin or a gap-junction by the tissue at the stimulation site to increase the conductivity of the tissue at the stimulation site and create a preferential conduction pathway between the stimulation site and at least one of a bundle of His or a Purkinje fiber of a heart of the patient, as recited by claim 46. No new matter has been added by the new claims.

CONCLUSION

All claims in this application are in condition for allowance. Applicant respectfully requests reconsideration and prompt allowance of all pending claims. Please charge any additional fees or credit any overpayment to deposit account number 50-1778. The Examiner is invited to telephone the below-signed attorney to discuss this application.

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